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| 10/551,988 | 10/05/2005 | Gerhard Hamprecht | 3165-137 | 6444 |
| 6449 7590 05/27/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005 | | | | |
| EXAMINER MABRY, JOHN | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/551,988

Applicant(s)

HAMPRECHT ET AL.

Examiner

John Mabry, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19, 22, 23 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) 20, 21 and 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19, 22, 23 and 28-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/05/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Examiner's Response

Applicant's response on April 4, 2008 filed in response to the Election/Restriction dated March 14, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group III with traverse.

The Applicant argues that the restriction was not appropriate. The Applicant requested that compound/composition, method of treatment and process of making claims of Formula I be examined together (Groups I-VII, IX and XI). The Applicant alleges that Examiner "directly" went "against the proceedings at the International Stage." The Examiner respectfully directs the Applicant to the portions of the MPEP that addresses this issue (see MPEP 1893.03 (e) – below. The Examiner has properly followed US restriction practice (see MPEP Chapter 800). Respectfully, the Examiner re-asserts that the Election/Restriction was properly restricted.

The examiner may adopt any portion or all of the report on patentability of the IPEA or ISA upon consideration in the national stage so long as it is consistent with U.S. practice. The first Office action on the merits should indicate the report on patentability of the IPEA or ISA has been considered by the examiner. The indication may be a mere acknowledgement.

However, the Examiner has further considered Applicant's arguments and has broadened the scope of the variable Q of Formula with respect to elected Group III. Q of Group III is now defined as: Q6, Q20, Q23, Q24, Q25, Q21 and Q27.

The Examiner has noticed an error in the restriction requirement in the definition of Y as defined as $Y = -CO_2R_1$, $-COSR_1$, $-SO_2NR_1R_2$, $-CONR_1R_2$ where in $R_2 = H$, alkyl, R_1 and R_2 cannot combine to form any cycle. Upon initial review prior to examination, the Examiner noticed that the definition of Y of restriction requirement fell outside the scope of the claims. The Examiner has revised the definition of Y to fit within Applicant's claimed invention. Taking into account the most recently amended claims, Y has been revised to be $Y = -CO_2R_1$ and $-COSR_1$.

The elected group III currently reads as:

- III. Claims 16-19, 22-23 and 28-39 are drawn to compounds and compositions of Formula I, wherein $X_1 = H$, halogen, $X = Cl$, $X_3 = H$, C1-C6 alkyl, $A = O$, $B = O$, S, $Y = -CO_2R_1$, $-COSR_1$ and $Q = Q_6, Q_{20}, Q_{23}, Q_{24}, Q_{25}, Q_{21}$ and Q_{27} wherein substituents on $Q = H$, alkyl, haloalkyl, hydroxyl. A further election of single disclosed species is required.

Note: Due to the error of Y, the elected species, Example No. 5 - which appears on pages 112 and 113 of Specification, does not fit within elected group. However, the elected species was for search purposes only. Applicant is considered in compliance of restriction requirement rules.

Thus, the restriction requirement is deemed proper and **FINAL**.

In view of this response, the status of the rejections/objections of record is as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being "an intended use" claim. The recitation of an intended use, chemical activity or functional description of some "additional" property for a compound (or moiety/functionality attached to the chemical core) or composition containing same in dependent claim, must result in a tangible structural difference between the product of the independent claim and the product set forth in the dependent claim. In the absence of said structural difference between the product of the independent claim and that of the dependent claim, said dependent claim is seen to be a substantial duplicate, and the said recitation is not afforded critical weight and fails to further limit the product in said dependent claim.

Claims 28-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Said claims need to be completely independent of Specification. Claims should not refer to Specification which can be included in claim.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-19, 22-23 and 28-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for X3 being H, unsubstituted alkyl, R1 being unsubstituted alkyl, phenyl-C1-C4-alkyl, unsubstituted cycloalkyl, Q being Q21 and substituents on Q being H, alkyl, haloalkyl, hydroxyl, but **does not** reasonably provide enablement for R1 being and that is substituted by the following:

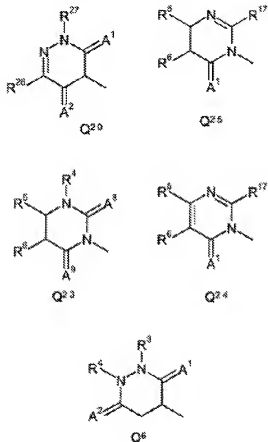
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R¹ is halogen, hydroxyl, C₃-C₇-cycloalkyl, C₃-C₇-cycloalkyl-C₁-C₄-alkyl, C₂-C₈-alkenyl, C₃-C₇-cycloalkenyl, C₃-C₈-alkynyl, C₁-C₈-alkoxy, C₃-C₇-cycloalkyloxy, C₂-C₈-alkenyloxy, C₃-C₈-alkynyloxy, aryl, aryloxy, aryl-C₁-C₄-alkyl;

where the 13 last mentioned radicals for their part may be partially or fully halogenated and/or may carry one to three substituents selected from the group consisting of cyano, NO₂, hydroxyl, C₁-C₈-alkyl, C₁-C₈-haloalkyl, C₃-C₇-cycloalkyl, C₁-C₈-alkoxy, C₁-C₈-haloalkoxy, C₃-C₇-cycloalkyloxy, C₂-C₈-alkenyloxy, C₃-C₈-alkynyloxy, C₁-C₈-alkylthio, C₁-C₈-haloalkylthio, amino, C₁-C₈-alkylamino, di(C₁-C₈-alkyl)amino, C₁-C₈-alkylsulfanyl, C₁-C₈-haloalkylsulfanyl, C₁-C₈-alkylsulfonyl, C₁-C₈-haloalkylsulfonyl, C₁-C₈-alkoxysulfonyl, formyl, C₁-C₈-alkylcarbonyl, C₁-C₈-haloalkylcarbonyl, C₂-C₈-alkenylcarbonyl, C₃-C₈-alkynylcarbonyl, carboxy, C₁-C₈-alkoxycarbonyl, C₁-C₈-haloalkoxycarbonyl, C₂-C₈-alkenyloxy carbonyl, C₃-C₈-alkynyloxy carbonyl, mercaptocarbonyl, C₁-C₈-alkylthiocarbonyl, C₁-C₈-haloalkylthiocarbonyl, C₂-C₈-alkenylthiocarbonyl, C₃-C₈-alkynylthiocarbonyl, aminocarbonyl, C₁-C₈-alkylaminocarbonyl, di(C₁-C₈-alkylamino)carbonyl, C₁-C₈-haloalkylaminocarbonyl, di(C₁-C₈-haloalkylamino)carbonyl, C₂-C₈-alkenylaminocarbonyl, di(C₂-C₈-alkenylamino)carbonyl, C₃-C₈-alkynylaminocarbonyl, di(C₃-C₈-alkynylamino)carbonyl, phenyl, phenoxy, phenyl-C₁-C₄-alkyl and phenyl-C₁-C₄-alkoxy;

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Q being:



and X3 being:

X³ is cyano, C₁-C₈-alkoxy-C₁-C₄-alkyl, C₃-C₇-cycloalkyl, C₃-C₈-alkenyl, C₃-C₈-alkynyl or phenyl-C₁-C₄-alkyl, where the phenyl radical for its part may be partially or fully halogenated and/or substituted by one to three radicals selected from the group consisting of C₁-C₈-alkyl and C₁-C₈-alkoxy;

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Specification does not provide any support for said variables at R1, X3 and Q positions. Pages 94 (Process A), 100 (Process B), 102 (Process C), 104 (Process D), 106 (Process E) of the Specification describe starting materials and methods for synthesis of compounds wherein R1, X3 and Q (as previously mentioned), but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R1, X3 and Q as listed above.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted benzenesulfonamide compounds are embraced.

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(2) The nature of the invention: The invention is a highly substituted benzenesulfonamide compounds.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 94 (Process A), 100 (Process B), 102 (Process C), 104 (Process D), 106 (Process E) of the Specification describe starting materials and methods for synthesis of compounds wherein R1, X3 and Q (as previously mentioned), but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R1, X3 and Q as listed above. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula I. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when

determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In *re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: So far as the examiner is aware, no substituted benzenesulfonamide compounds of general formula I wherein R₁, X₃ and Q equals the aforementioned of any kind have been made or used.

It is not trivial to experimentally interchange any and all of the many substituents that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made,

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many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see "Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim.

(6) Working Examples: Applicant shows examples 3.1-3.42 (Table 3 on page 115-116) but no working examples were shown wherein R1, X3 and Q equal aforementioned substituents have been made or used of any kind.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

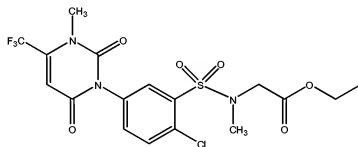
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-19, 22-23 and 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strunk et al (US 5,169,430) (PTO-1449).

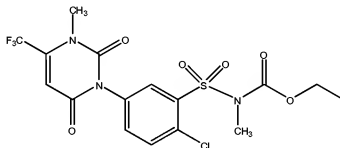
The instant application claims compounds and pharmaceutical compositions of Formula I wherein X1/Y1=halogen, X3=CH3, Q=Q21, Y=C(O)OC2H5.

Scope & Content of Prior Art MPEP 2141.01

Strunk discloses compounds and pharmaceutical compositions of Formula I wherein X1/Y1=halogen, X3=CH₃, Q=Q21, Y-R1=-C(O)O-C₂H₅ (see Compound No. 41, column 23/24, Table I).

**Differences between Prior Art & the Claims MPEP 2141.02**

Strunk differs from the instant application at the -N-Y- position:
Strunk's -NCH₃-CH₂-CO₂CH₂CH₃ versus Applicants' -NCH₃-CO₂CH₂CH₃

**Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413**

An artisan of ordinary skill would be motivated to extend the -N-Y- position by one -CH₂- group for a herbicidal use as a method of controlling weeds as disclosed by

Strunk. The current application claims the same method of controlling unwanted vegetation using compounds of Formula I.

The MPEP 2144.09 which states: Compounds which are homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

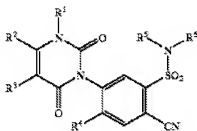
Claims 16-19, 22-23 and 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andree et al (US 6,107,252) in view of Strunk et al (US 5,169,430) (both in PTO-1449).

The instant application claims compounds and pharmaceutical compositions of Formula I wherein $X1/Y1$ =halogen, $X3=CH_3$, $Q=Q21$, $Y=-C(O)OC_2H_5$.

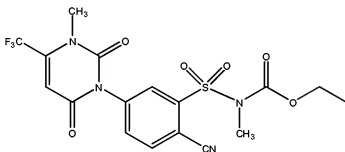
Scope & Content of Prior Art MPEP 2141.01

Andree discloses compounds and pharmaceutical compositions of Formula I wherein $X1=H$, $Y1=cyano$, $X3=CH_3$, $Q=Q21$, $Y-R1=-C(O)O-C_2H_5$ (see Compound No. 41, column 23/24, Table I).

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which would yield (see column 3, line 47 $-\text{C}(\text{O})-\text{OC}_2\text{H}_5$):



Differences between Prior Art & the Claims MPEP 2141.02

Andree differs from the instant application at the X2 position:

Andree's $-\text{CN}$ versus Applicants' $-\text{Cl}$. However, Strunk discloses similar structure and teaches that X2 can be cyano or halogen (see column 2, line 4).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

An artisan of ordinary skill would be motivated to combine the teachings of Andree view of Strunk. Andree clearly teaches the structures as claimed in the instant application with the exception of the cyano group on the phenyl ring. Strunk clearly teaches the equivalency of halogen and CN at the X2 position. Strunk and Andree discloses compounds for herbicidal use. The current application claims the same

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method of controlling unwanted vegetation using compounds of Formula I. For the aforementioned reasons, it would be obvious to combine the teaching of Andree and Strunk to make compounds of Formula I for herbicidal use.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable

- solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 214.3 for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144-§2144.09 for additional guidance regarding support for obviousness determinations.

The aforementioned reasons above describe rationales that support a conclusion of obviousness based upon the KSR International Co. v. Teleflex Inc. decision. At least letters (A)-(B) and (D)-(G) rationale is supported using the references above.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/John Mabry, PhD/

Examiner

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/Rita J. Desai/

Primary Examiner, Art Unit 1625